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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|----------------------|----------------------|---------------------------------------|------------------|
| 10/695,636 | 10/28/2003 | Mark A. Tapsak | DEXCOM.028A - | 5384 |
| 20995 7590 03/14/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET | | | EXAMINER | |
| | | | MOORE, MARGARET G | |
| FOURTEENTH FLOOR IRVINE, CA 92614 | | | ART UNIT | PAPER NUMBER |
| , | | | 1712 | |
| <u>,</u> | ···· | | · · · · · · · · · · · · · · · · · · · | |
| SHORTENED STATUTOR | Y PERIOD OF RESPONSE | NOTIFICATION DATE | DELIVERY MODE | |
| 3 MONTHS 03/ | | 03/14/2007 | ELECTRONIC | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/14/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com eOAPilot@kmob.com

| | Application No. | Applicant(s) | | | |
|---|---|---|--|--|--|
| | 10/695,636 | TAPSAK ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | Margaret G. Moore | 1712 | | | |
| The MAILING DATE of this communication Period for Reply | appears on the cover sheet wit | h the correspondence address | | | |
| A SHORTENED STATUTORY PERIOD FOR RE WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFI after SIX (6) MONTHS from the mailing date of this communication - If NO period for reply is specified above, the maximum statutory pe - Failure to reply within the set or extended period for reply will, by st Any reply received by the Office later than three months after the mearned patent term adjustment. See 37 CFR 1.704(b). | G DATE OF THIS COMMUNIC R 1.136(a). In no event, however, may a re riod will apply and will expire SIX (6) MON tatute, cause the application to become AB | CATION. Poply be timely filed ITHS from the mailing date of this communication. ANDONED (35 U.S.C. § 133). | | | |
| Status | | | | | |
| 1) Responsive to communication(s) filed on 1 | 2 January 2007. | | | | |
| <u> </u> | | | | | |
| 3) Since this application is in condition for allo | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | |
| closed in accordance with the practice und | er <i>Ex parte Quayle</i> , 1935 C.D. | . 11, 453 O.G. 213. | | | |
| Disposition of Claims | | | | | |
| 4)⊠ Claim(s) <u>1 to 25, 135 to 144</u> is/are pending | in the application. | | | | |
| 4a) Of the above claim(s) <u>1 to 23, 135 to 14</u> | | deration. | | | |
| 5) Claim(s) is/are allowed. | | | | | |
| 6)⊠ Claim(s) <u>24, 25</u> is/are rejected. | | | | | |
| 7) Claim(s) is/are objected to. | | | | | |
| 8) Claim(s) are subject to restriction ar | nd/or election requirement. | | | | |
| Application Papers | | · | | | |
| 9) The specification is objected to by the Exan | niner. | | | | |
| 10) The drawing(s) filed on is/are: a) | | by the Examiner. | | | |
| Applicant may not request that any objection to | the drawing(s) be held in abeyan | ce. See 37 CFR 1.85(a). | | | |
| Replacement drawing sheet(s) including the con | rrection is required if the drawing(| s) is objected to. See 37 CFR 1.121(d). | | | |
| 11)☐ The oath or declaration is objected to by the | e Examiner. Note the attached | Office Action or form PTO-152. | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for fore a) All b) Some * c) None of: | - | 119(a)-(d) or (f). | | | |
| 1. Certified copies of the priority docum | | | | | |
| 2. Certified copies of the priority docum | | · · · · · · · · · · · · · · · · · · · | | | |
| 3. Copies of the certified copies of the p | • | received in this National Stage | | | |
| application from the International Bu * See the attached detailed Office action for a | • | received | | | |
| dec the attached detailed office detail for a | | · · | | | |
| Attachment(s) | | | | | |
| 1) Notice of References Cited (PTO-892) | | ummary (PTO-413) | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) | 5) 🔲 Notice of In |)/Mail Date formal Patent Application | | | |
| Paper No(s)/Mail Date | 6) Other: | · | | | |

Application/Control Number: 10/695,636

Art Unit: 1712

1. Newly submitted claims 1 - 23 and 135 - 144 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these claims are directed to an analyte sensor comprising an electrode and a membrane disposed over the electrode while the claims under consideration previously were drawn to a membrane. These groups of claims fall into the category of intermediate/final product.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1 to 23 and 135 to 144 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

- 2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 3. Claims 24 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Kennedy.
- 4. Claims 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Keogh et al.
- 5. These rejections are maintained from the previous office action. Applicants' sole traversal of the claim rejections is that these claims, directed to a biosensor and drug delivery device, are not anticipated by Kennedy or Keogh. This mere statement is not sufficient. As noted previously it is the Examiner's position that the membranes in Kennedy et al. and Keogh et al. anticipate the biocompatible membrane required by claims 24 and 25. The claimed biosensor and device are defined solely by the membrane therein. In other words, the claims require only the membrane as defined and nothing else. The language "biosensor" and "implantable drug delivery device" does not lend any structural limitation to these

Application/Control Number: 10/695,636

Art Unit: 1712

claims. Since the membrane is anticipated by the prior, the biosensor and device of claims 24 and 25 are likewise anticipated.

6. Claims 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Antwerp.

In an effort to distinguish the claims from the teachings in Van Antwerp et al., applicants have limited the optional substituent groups. A full reading of this claim language indicates that the it is the terminal groups of the *backbone* that are so limited and that the *backbone* has alternating silicon and oxygen atoms. The Examiner notes that it is not the silicone polymer per se that must have these terminal groups and that the silicone polymer *comprises* the backbone. This means that 1) the silicone polymer can contain other units such as polyureathane since *comprising* opens the claims to other units and 2) that only the terminal groups on the alternating silicon and oxygen backbone must be selected from the moieties claimed.

With this in mind, note that the polyurethane polysiloxane polymer in Van Antwerp is prepared from a polysiloxane having amine or hydroxyl substituent groups. See for instance Figure 5 and column 7, lines 33 and on. Thus the terminal groups of the alternating silicon and oxygen *backbone* will meet the new limitations in this claim.

Note for instance Example 1. This reacts an amino terminated siloxane and thus the terminal groups of the alternating silicon and oxygen backbone will substituted with an amino group.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory

Art Unit: 1712

period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Margaret G. Moore whose telephone number is 571-272-1090. The examiner can normally be reached on Monday to Wednesday and Friday, 10am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Margaret G. Moor Primary Examiner

Art Unit 1712

mgm 3/9/07